REMARKS

By the foregoing amendment, claims 1, 2, 6, and 7 have been amended, and claims 5 and 10-20 have been canceled.

The subject matter previously recited in claim 5 has been incorporated into claim 1. The other amendment to claim 1 finds support throughout the specification, and specifically for example, in the Examples and Table 1.

Objection to the claims

The Action objects to claims 6, 11, and 12 for reciting "over" instead of "overall" and "cm/mm" instead of "cm/min." In response, Applicants have amended claim 6 and note that claims 10-20 have been canceled. Applicants respectfully request withdrawal of the objections.

Claim Rejections under 35 U.S.C. § 102(b)

The Office Action rejects claims 1, 2, 6, and 7 under 35 U.S.C. § 102(b) as anticipated by Kim et al. (WO2002/087735; as presented by U.S. Patent Application Publication No. 2004/0167237 A1 to Kim et al.) Applicants respectfully submit that Kim et al. fails to anticipate the presently claimed invention for at least the following reasons.

A hollow fiber membrane comprised of polysulfone-based resin and polyvinylpyrrolidone K-90 exhibits high performance in removing undesired substances and is the best blood purification membrane for reducing the adsorption of protein from blood to the membrane. In order to reduce the protein adsorption amount to the hollow fiber membrane, it is desirable to set the polyvinylpyrrolidone concentration in the hollow fiber membrane in the range of 3.0 to 5.0 wt%. Applicants respectfully submit that Kim et al. fails to disclose a membrane having these features or advantages.

Kim et al. discloses, in comparative example 1, a hollow fiber made from a raw spinning solution comprising polysulfone-based resin, polyvinylpyrrolidone of unknown molecular weight, and N-methyl-2-pyrrolidone. Applicants note that N-methyl-2-pyrrolidone is the solvent

that shows the strongest dissolving power against polysulfone-based resin and polyvinylpyrrolidone. For example, at room temperature, the dissolving power of N-methyl-2-pyrrolidone against polysulfone-based resin and polyvinylpyrrolidone is 1.5 times higher than that of dimethyl acetamide (the presently claimed solvent). Using N-methyl-2-pyrrolidone, it is difficult to keep the polyvinylpyrrolidone concentration in the hollow fiber membrane in the range of 3.0 to 5.0 wt%. Moreover, the polyvinylpyrrolidone is more likely to be retained in the hollow fiber as its molecular weight increases. Applicants respectfully note that Kim et al. does not disclose the molecular weight of the polyvinylpyrrolidone in comparative example 1. On the other hand, Applicants' claimed invention requires polyvinylpyrrolidone K-90 and further requires that the concentration of the polyvinylpyrrolidone is kept in the range of 3.0 to 5.0 wt% (also claimed, but not disclosed in Kim et al.), which is possible through the use of Applicants' specifically claimed polyvinylpyrrolidone.

Still further, Applicants note that in the present invention, the zeta potential on the inner surface of the hollow fiber can be achieved by running a raw spinning solution comprising polysulfone-based resin, polyvinylpyrrolidone K-90, and dimethyl acetamide through an air gap whose relative humidity is 75% to 90% for 0.4 seconds or more. Kim et al., on the other hand, discloses in comparative example 1 that the extruded hollow fiber was caused to run through a hood saturated with water vapor, which is believed to be greater than 95%, and which is outside the presently claimed range of humidity. Applicants respectfully submit that this is a difference in the process by which the hollow fiber membrane of the present invention is made, and due at least to this difference, the zeta potential of the hollow fiber obtained in the present invention is different from that obtained by Kim et al.

Applicants note that Kim et al. discloses in Table 1 in comparative example 1 that the zeta potential of the hollow fiber is -1 mV. Applicants note that this value is obtained by a different method than that used in the present specification: a method without using a sample with an embedded resin on the outer side for allowing the electrolyte solution to flow through only the inside of the hollow fiber. Moreover, Kim et al. discloses in the Abstract that the dense layer is non-charged at least on the outermost surface (inner membrane surface) and this serves as a size barrier. Applicants respectfully submit that the hollow fiber of Kim et al. cannot be

deemed to have a zeta potential higher than -3.0 mV and less than 0 mV, as those values are tested in the present invention.

In conclusion, Applicants respectfully submit that 1) the Kim et al. membrane is not obtained by running a raw spinning solution comprising polysulfone-based resin, polyvinylpyrrolidone K90, and dimethyl acetamide, through an air gap whose relative humidity is 75% to 90% for 0.4 seconds or more, 2) the Kim et al. membrane does not have a polyvinylpyrrolidone concentration in the hollow fiber membrane of between 3.0 and 5.0 wt%, and 3) the Kim et al. membrane does not exhibit a zeta potential on the inner surface thereof of greater than -3.0 mV but less than 0 mV at pH 7.5, when measured using a sample with an embedded resin on the outer side for allowing the electrolyte solution to flow through only the inside of the hollow fiber, and using a 0.001 mol/l potassium chloride aqueous solution as an electrolyte solution. For at least these reasons, Applicants submit that the Patent Office has failed to establish a *prima facie* case of anticipation and submit that the rejection over Kim et al. must be withdrawn.

Claim Rejections under 35 U.S.C. § 103(a)

The Office Action raises the following obviousness rejections:

The Action rejects claim 5 under 35 U.S.C. 35 U.S.C. § 103(a) as being unpatentable over Kim in view of U.S. Patent No. 6,355,730 B1 to Kozawa et al.; and

the Action rejects claims 8 and 9 under 35 U.S.C. 35 U.S.C. § 103(a) as being unpatentable over Kim in view of RE 36,914 to Carlsen et al.

The Action asserts that the secondary references, Kozawa et al. and Carlsen et al., cure the deficiencies of Kim et al. with regard to dependent claims 5, 8, and 9. The Action asserts that Kozawa et al. cures Kim et al.'s deficiencies with respect to a hollow fiber having a polyvinyl pyrrolidone concentration in the hollow fiber membrane in the range of 3.0 to 5.0 wt% and Carlsen et al. cures the deficiencies of Kim et al. relating to a blood purification apparatus comprising a hollow fiber membrane, installed in a cylindrical container.

In view of the foregoing remarks regarding the rejections under § 102, Applicants submit that Kim et al. fails to disclose all of the elements of the presently claimed invention, including for example, the claimed zeta potential. Applicants respectfully submit that neither Kozawa et al. nor Carlsen et al. cure this deficiency. Thus, the combination of Kim et al. with either Kozawa et al. or Carlsen et al. fails to render obvious claims 8 or 9.

Still further, Applicants provide the following comments. An advantage of the present invention is the provision of hollow fiber membranes with enhanced phosphorus-removing performance without impairing antithrombogenecity, and the provision of a blood purification apparatus using the hollow fiber membrane. These advantages are obtained by the specifically recited elements of the present claims. The hollow fiber membrane of the present invention has excellent performance in fractionating into low-molecular-weight proteins and albumin as well as in removing phosphorus. A blood purification apparatus using the presently claimed membrane is useful for ameliorating dialysis amyloidosis and the like and can effectively contribute to amelioration of long-term dialysis complications.

Kim et al., on the other hand, seeks to provide asymmetric porous films which are suitable for blood dialysis, plasma separation, etc., having the following properties: excellence in performance of selectively separating plasma protein, exhibit little endogenous coagulation, complement, or quinine activity, and have an extremely high biocompatibility. (Abstract and pagraphs 0019 and 0020.) Kozawa et al. seeks to provide a selectively permeable membrane having the following properties: permeability to albumin is minimized while permeability to water is kept at a high level, and ability to remove medium-to-high molecular weight uremia-causing protein is enhanced (page 2, lines 32-39).

Importantly, neither Kim et al. nor Kozawa et al. seeks to provide a hollow fiber membrane or apparatus capable of the features of the presently claimed invention: enhanced phosphorus-removing performance without compromising antithrombogenecity. Applicants respectfully submit that these features are not taught or suggested by Kim et al. or Kozawa et al., and a person of skill in the art would not modify the teachings of either of these cited references to arrive at Applicants' claimed invention.

Still further, Applicants note that the presently claimed hollow fiber membrane is obtained by running a raw spinning solution comprising polysulfone-based resin, polyvinylpyrrolidone K90, and dimethyl acetamide, through an air gap whose relative humidity is 75% to 90% for 0.4 seconds or more. Neither Kim et al. nor Kozawa et al. discloses or suggests a hollow fiber membrane made by this process. For this reason as well, the combination of Kim et al. with Kozawa et al. cannot render obvious the presently claimed invention.

Applicants also wish to point out that Kim et al. discloses that the dense layer non-charged at least on the outermost surface (the inner surface) serves as a size barrier, while the part of the film other than the outermost surface serves as a charge barrier. (See Abstract.) On the other hand, the hollow fiber membrane of the present invention has a useful charge (zeta potential) on the inner surface. Applicants respectfully submit that this difference is not taught or suggested by Kim et al. or Kozawa et al.

Applicants also respectfully note that there is no reason a person of ordinary skill in the art would combine the teachings of Kim et al. with those of Kozawa et al. The Action states that Kozawa et al. teaches that its specifically recited polyvinylpyrrolidone concentrations are useful for producing membranes useful in dialysis, and that accordingly, a person skilled in the art would combine the teachings of Kim et al. with those of Kozawa et al. (Office Action, bottom of page 5.) Applicants respectfully disagree. As the Action has stated, Kim et al. already teaches membranes allegedly useful in dialysis. A person of skill in the art, seeking to make dialysis membranes, would not look beyond Kim et al. That is, if these two references are read for what they fairly convey to a person of ordinary skill, then there is nothing in Kim et al. that would cause a person of ordinary skill in the art to combine its teachings of those with Kozawa et al., or vice versa.

Applicants respectfully submit that Carlsen et al., relied upon by the Action in the rejection of claims 8 and 9, which depend ultimately from claim 1, fails to remedy the deficiencies of Kim et al. and Kozawa et al. that are discussed above. Thus, Kim et al., in combination with Kozawa et al., or Carlsen et al., fails to render obvious claims 8 or 9. Applicants respectfully request withdrawal of the rejection of claims 8 and 9 for obviousness.

Applicants respectfully request withdrawal of the obviousness rejections.

CONCLUSION

In view of the foregoing, the Examiner is respectfully requested to reconsider and withdraw the rejections of record, and allow all the pending claims.

Should there be any questions, the Examiner is invited to contact the undersigned at the below listed telephone number.

Respectfully submitted,
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